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Patent

Remarks

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. The instant method and apparatus claims refer to devices comprising one or more capillary channels in which the relative hydrophobicity of regions within at least one capillary channel differs. In certain embodiments, this differing hydrophobicity is used to control the rate and/or direction of fluid flow through the devices.

Prior to the present submission, Claims 1-5 and 7-18 were pending in the application. By the present submission, Claim 13 has been cancelled, and Claims 1, 7, and 14 amended. Exemplary support for the amendment to Claims 1 and 14 may be found in the specification, *e.g.*, on page 34, lines 5-9, which describes a single step flow device where only the sample fluid needs to be added. Claim 7 as amended incorporates the limitations of now cancelled Claim 13.

Notwithstanding the foregoing, Applicant expressly reserves the right to pursue subject matter no longer claimed in the instant application in one or more applications that may claim priority hereto. Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1-18 under 35 U.S.C. §102(e), as allegedly being anticipated by Kuhn *et al.*, U.S. Patent 5,202,268 ("the '268 patent").

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*, MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. *See, e.g., In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

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The Examiner points with particularity to the disclosure of a liquid flow path in the '268 patent through two porous layers, and to claim 4 of the '268 patent, which states that one of the layers may be hydrophilic and the other hydrophobic. The rejection is premised on an assertion that the flow path through these porous layers is equivalent to flow through the "capillary channel" of the instant claims. *See, e.g.*, Paper no. 9, page 4 ("[t]he taught flow path has been read on the claimed capillary channel . . ."). But, as discussed in detail previously by Applicant, the porous layers disclosed in the '268 patent are not equivalent to a capillary channel.

As evidence of this fact, Applicant provided a declaration of one of skill in the art, Dr. Kenneth F. Buechler, describing how the term "capillary channel" should be properly interpreted. In particular, Dr. Buechler discussed the common meaning of the term "channel," and explained that the skilled artisan would understand that flow through a porous material as disclosed in the '268 patent is both tortuous and random, and that, therefore, a porous material is not equivalent to a "capillary channel." Dr. Buechler also pointed out that the present specification uses the term "capillary channel" consistently with this definition, noting that the instant specification clearly distinguishes between porous materials and capillary channels.

The Examiner has previously acknowledged the correctness of the Buechler declaration with respect to the plain meaning of the term "capillary channel" used in the claims. *See, e.g.*, office action mailed January 14, 2004, page 4 ("[t]he office agrees with all of the characterization made about what is intended by a channel."). Nevertheless, in the present Office Action, the Examiner declines to accept this established plain meaning of the term when considering the claimed invention ". . . [i]n the absence of the specification providing a positive description of what a capillary channel is. . . ." Office Action, page 4. The Examiner, however, has offered no evidence of record that contradicts the conclusions of the Buechler declaration as to how the skilled artisan would interpret the term "capillary channel."

Moreover, the Examiner's assertion that "it is insufficient for Applicant to pick a definition from the specification of what the capillary channel is not" (Office Action, page 4) indicates a misunderstanding. Applicant has not "picked a definition from the specification";

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rather, Applicant has cited to evidence regarding the ordinary and customary meaning of the term "capillary channel" as the skilled artisan would interpret that term. Applicant's evidence is the only such evidence of record in the case and should control.

It is well established that terms in a claim must be interpreted as they would be by those of skill in the art. *See*, MPEP §§ 2111 and 2111.01. The Examiner's interpretation is contrary to the plain meaning of "capillary channel" given to the term by those of skill in the art, to the teachings of the instant specification, and to the only objective evidence of record on the point. Indeed, the rejection simply reads the term out of the claim, asserting that because both a capillary channel and a porous member each might "comprise a capillary region," each must be "indistinguishable." Office Action, page 4. Applicant respectfully submits that, by failing to consider the plain meaning of the claims, the rejection is fatally flawed.

Accordingly, the '268 patent does not anticipate the claims because it fails to teach each and every limitation. Thus, the Examiner is requested to reconsider and withdraw the rejection over Kuhn *et al.*

Applicant also notes that the Examiner has failed to indicate how the cited publication reads on the various dependent claims. For example, the Examiner has not indicated how the cited publication reads on claims 3, 7 and 12, which indicate that a hydrophobic region is used to delay fluid flow until rendered hydrophilic. As discussed by Dr. Buechler in paragraph 9 of his declaration, the '268 patent does not disclose these elements of the claims. Applicant previously requested that the Examiner indicate where such elements may be found in the cited patent, so that Applicant might have a reasonable opportunity to respond. However, the present Office Action provides no further clarification on this point. The dependent claims should be indicated as allowable absent the citation of prior art teaching disclosing the additional elements.

Because the cited '268 patent fails to teach each and every element of the present claims, Applicant respectfully submits that no *prima facie* case of anticipation has been established. Applicant therefore requests that the rejection under 35 U.S.C. §102 be reconsidered and

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withdrawn.

Applicant also respectfully traverses the rejection of claims 1-18 under 35 U.S.C. §102(e), as allegedly being anticipated by Romanauskas *et al.*, U.S. Patent 4,762,683 ("the '683 patent").

The invention presently described in Claims 1 and 14 (and those claims depending therefrom) distinguishes from the device disclosed in the '683 patent, in that the present invention refers to methods and devices configured such that, upon introduction of fluid to the device, fluid flows through a first hydrophilic capillary region to contact a second hydrophobic capillary region without a requirement for further manipulation of the device. In contrast, the '683 patent refers to centrifugally-driven devices in which fluid is introduced into a central receptacle of the device. Only by rotation of the device, creating centrifugal force to drive fluid flow to the outer portions of the device does fluid flow to a capillary region. *See, e.g.*, '683 patent, column 4, lines 23-45.

The invention presently described in Claim 7 (and those claims depending therefrom) distinguishes from the device disclosed in the '683 patent, in that the present invention refers to methods in which a hydrophobic region alters the rate of flow through a device by retarding flow until rendered hydrophilic. In contrast, the '683 patent refers to centrifugally-driven devices in which flow is completely and permanently stopped by a hydrophilic region that is never rendered hydrophilic. *See, e.g.*, '683 patent, column 4, lines 46-51.

Because the cited '683 patent fails to teach each and every element of the present claims, Applicant respectfully submits that no *prima facie* case of anticipation has been established. Applicant therefore requests that the rejection under 35 U.S.C. §102 be reconsidered and withdrawn.

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Patent**CONCLUSION**

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

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